REMARKS

Claims 1-15 are pending. Claims 1, 6, and 11 have been amended. Specifically, claims 1, 6, and 11 have been amended to provide the full name of "Growth Differentiation Factor 8," as suggested by the Examiner. Claims 1, 6, and 11 have been further amended to provide the step of correlating the identification of the compound with the expression of the gene, as suggested by the Examiner (*i.e.*, to specify that the "difference in the expression of the gene compared to the control identifies the compound as capable of regulating GDF-8 expression"). Claim 11 has been further amended to remove the term "90% identical" and to specify a portion of an isolated GDF-8 promoter comprising the nucleotide sequence of SEQ ID NO:1, 2, or 3. Support for the foregoing amendments can be found throughout the application as originally filed.

The foregoing claim amendments should not be construed as an acquiescence to any of the Examiner's rejections and have been made solely to expedite prosecution. Applicants reserve the right to pursue claims to the canceled subject matter, or any subject matter which they are entitled to claim, in this or a separate application. No new matter has been added.

Claim Objections

Clams 1, 6, and 11 are objected to because, according to the Examiner, "'GDF-8' is an indefinite term." Claims 1, 6, and 11 have been amended to provide the full name of "Growth Differentiation Factor 8," as suggested by the Examiner. Therefore, this rejection is moot.

Rejection of Claims 1-15 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-15 are rejected as being incomplete. Independent claims 1, 6, and 11 have been amended to provide the step of correlating the identification of the compound with the expression of the gene (*i.e.*, to specify that the "difference in the expression of the gene compared to the control identifies the compound as capable of regulating GDF-8 expression"). Accordingly, this rejection is moot.

Rejection of Claims 6-15 Under 35 U.S.C. § 112, First Paragraph

Claims 6-15 are rejected as not meeting the written description standard. Specifically, the Examiner states that "[c]laims 6 and 11 are broadly drawn, such that they apply to methods of identifying compounds which regulate transcription from a genus of promoters comprising

isolated nucleic acids which are at least 90% identical to SEQ ID NO:1." Applicants respectfully traverse this rejection.

From the outset, Applicants note that claims 6-10 are drawn to methods which encompass promoters comprising isolated nucleic acids which are ***at least 95% identical*** to SEQ ID NO:1. Such molecules are fully described in the present specification. In particular, Applicants respectfully direct the Examiner's attention to Example 14 of the *Revised Interim Written Description Guidelines Training Materials* (published January 5, 2001; http://www.uspto.gov/web/menu/written.pdf), which provides that a claim directed to variants of a protein that are at least 95% identical to a particularly disclosed sequence and that have a particularly specified activity in combination with an accompanying specification that discloses a single species falling with the claimed genus, satisfies the requirements of 25 U.S.C. §112, first paragraph, for written description. Therein, the Office concludes that "the genus of proteins that must be variants . . . does not have substantial variation since all the variants must possess the specific catalytic activity and must have at least 95% identity to the reference sequence." The rationale behind the foregoing conclusion, as presented by the *Written Description Guidelines*, is that "[t]he single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which Applicant provides for identifying all of the at least 95% identical variants...which are capable of the specified catalytic activity." Accordingly, one skilled in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus (*i.e.*, the sample claim meets the written description requirement of 35 U.S.C. §112, first paragraph). See, Training Materials, pages 53-55.

The subject matter as encompassed by the methods of claims 6-10 is analogous to the claim of Example 14 in the Guidelines in that the claims of the instant application are directed to a DNA having at least 95% identity to a reference sequence, namely SEQ ID NO:1, and having a specifically identified activity, namely the regulation of expression of a protein. As discussed above, since the species disclosed is representative of the claimed genus based, for example, on the defined structural and functional features, the claimed genus will not have substantial variation. Thus, it follows that since the genus is not widely variable, a single species (namely, SEQ ID NO:1) is sufficient to demonstrate possession. Furthermore, the instant specification sets forth methods for identifying all of the at least 95% identical variants of SEQ ID NO:1 which perform the claimed function.

Based at least on the foregoing, the present specification sufficiently describes the genus encompassed by claims 6-10 so as to convey with reasonable clarity to those skilled in the art that Applicants were in possession of the claimed invention.

Further, to expedite prosecution, independent claim 11 has been amended to remove the phrase "90% identical." Accordingly, this rejection is moot with respect to claims 11-15.

Rejection of Claims 1-15 Under 35 U.S.C. § 112, First Paragraph

Claims 1-15 are rejected as not being enabled. Specifically, the Examiner states that "the specification, while being enabling for *in vitro* methods of screening for modulators of GDF-8 promoter, does not reasonably provide enablement for *in vivo methods* of screening" (emphasis in original).

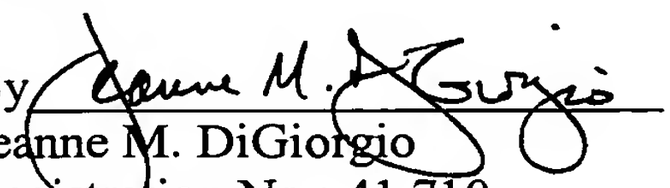
Applicants note that pending claims include the step of "contacting the promoter with the compound ***in a cultured cell*** such that the gene is transcribed and expressed." Such a step would occur outside a living organism. Accordingly, the claims are drawn to in vitro methods which, as indicated by the Examiner, are enabled.

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. MTN-027DV1CN.

Dated: December 10, 2007

Respectfully submitted,

By 

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